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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,348	02/24/2004	Susan Shelso	1001.1725101	8750
28075 7590 05/08/2008 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER				
SCHELL, LAURA C				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
05/08/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,348

Applicant(s)

SHELSON ET AL.

Examiner

LAURA C. SCHELL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 16, 17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12, 16, 17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al. (US Patent No. 5,316,706). Muni discloses the device substantially as claimed including a medical device for slidable use with a guidewire, the guidewire having a first diameter and a distal stop having a second diameter greater than the first diameter (the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition), the medical device comprising: an elongate

tubular member (Fig. 1) having a proximal end (near 22) and a distal end (near 20) with a guidewire receiving lumen extending therethrough (lumen 16 is perfectly capable of receiving a guidewire), a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (Fig. 1); and a tip (near 18) disposed at the distal end of the elongate tubular member and having a distal end (near 20), a proximal end (near 14) and a lumen therethrough (lumen 16 extends through the tip), the tip having an elastic portion (18) and a radially inextensible distal portion (14), wherein the tip comprises an amorphous polymer and the radially inextensible portion comprises a locally crystalline section thereof (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness).

Muni, however, does not disclose that the radially inextensible portion is distal to the elastic portion. Muni, does, however, disclose in col. 4, lines 18-22 that the catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. The examiner would also like to point out that the claim language does not require that the distal-most portion of the catheter is the radially inextensible ring, the language just requires that a portion of the tip distal to the elastic portion is radially inextensible. Therefore it would have been obvious to one of ordinary skill in the art due to this teaching to have made a portion distal of the

amorphous portion of the tip, crystalline, as Muni teaches that different portions of the catheter can be made to be soft or hard as desired, in order to provide a catheter that can be used in a variety of different procedures that a soft-tipped catheter could not.

Claims 9-12, 16, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. (US Patent No. 4,531,943) in view of Muni et al. (US Patent No. 5,316,706). Van Tassel discloses a medical device (Figs. 4 and 5) capable of use with a guidewire (the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition), the medical device comprising: an elongate tubular member (Figs. 4 and 5) having a proximal end (10) and a distal end (26) with a guide wire receiving lumen (lumen 11 is perfectly capable of receiving a guidewire) extending therethrough, a distal portion of the guidewire lumen having an inner diameter; and a tip (28) disposed at the distal end of the elongate tubular member and having a distal end (25), a proximal end (near 28) and a lumen therethrough, the tip having an elastic portion (portion 24) and a radially inextensible distal portion (30) distal of the elastic portion (col. 4, line 40 through col. 5 line 7). Van Tassel, however, does not disclose that the lumen is a guidewire receiving

lumen or that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof.

Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the amorphous portion of the tip, crystalline. The examiner would also like to point out that the claim language does not require that the distal-most portion of the catheter is the radially inextensible ring, the language just requires that a portion of the tip distal to the elastic portion is radially inextensible). Furthermore, the lumen disclosed by Van Tassel (11) is perfectly capable of receiving a guidewire therein. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Van Tassel with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened

tip for the catheter, especially since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

In reference to claim 10, Van Tassel discloses that the radially inextensible distal portion (30) is an extremity (Figs. 4 and 5).

In reference to claim 11, Van Tassel discloses that the extremity is a distal most extremity (Figs. 4 and 5).

In reference to claim 12, Van Tassel discloses that the radially inextensible distal portion comprises a ring (30) having a lumen (29) therethrough.

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Van Tassel.

In reference to claim 19, Van Tassel discloses that the radially inextensible distal portion comprises a non-compliant plastic band (col. 5, lines 2-7 disclose that it is a non-compliant band and col. 4, line 66 discloses it is made of plastic).

In reference to claim 20, Van Tassel further discloses that the tip further comprises a flexible portion (between 28 and 30) proximate the radially inextensible distal portion (30).

In reference to claim 21, Van Tassel also discloses that the radially inextensible distal portion is a distal-most extremity and wherein the flexible portion (portion designated generally as 24) is proximal of the radially inextensible distal portion, wherein the flexible portion tapers from a first outer diameter (diameter at 28) at a first location along the tip to a second outer diameter (diameter at 27; col. 4, lines 55-57)

less than the first outer diameter at a second location along the tip distal of the first location.

In reference to claim 22, Van Tassel further discloses wherein at the first location along the tip, the tip has a first thickness and a first inner diameter (Fig. 4 wherein the first location is at 28), and wherein at the second location along the tip distal of the first location (location at 27), the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (col. 4, lines 55-57 disclose that there is less material at 27 and Fig. 4 discloses that the inner diameter is greater here).

In reference to claim 23, Van Tassel discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 4).

Response to Arguments

The examiner acknowledges that the second rejection above was previously made in the office action mailed 4/30/2007 and the rejection was dropped once she had reviewed Applicant's arguments, Concerning Muni teaching that the distal tip of the catheter is soft and the body crystalline. The examiner and her supervisor, however, revisited the rejection from 4/30/2007 and believe that it should have been maintained and further, the independent claim 9 could also be rejected under Muni alone. The examiner reread the Muni reference and found support (col. 4, lines 18-22) for the catheter having varying regions of the soft amorphous polymer and crystalline/hardened

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sections, which the examiner and her supervisor believe make it obvious that it would have been obvious to one of ordinary skill in the art to have made the section distal to the amorphous polymer a crystalline section thereof. The examiner and her supervisor also believe that the rejection could be made under the Muni reference alone, in that the claim does not specifically recite the limitations of the guidewire. The examiner suggests that more structural limitations be added concerning the tip of the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767